REMARKS

Applicants added new claims 16- 27. Support for the amendment can be found, e.g., at pages 7-9 of the specification. Claims 1-27, of which claims 1 and 16 are in independent form, are presented for examination.

Claim 1 recites a bone graft substitute composition consisting essentially of calcium sulfate, a mixing solution, and a plasticizing substance. Claim 16 recites a bone graft substitute composition consisting of calcium sulfate, a mixing solution, and a plasticizing substance.

As described in Applicants' specification, in addition to being useable by itself, the claimed compositions can be used as a base or a carrier. The compositions allow a user to customize a mixed composition, e.g., on site and according to a desired application, by mixing the base with other materials such as allografts, antibiotics, and growth factors. The base compositions also have the advantages of having relatively low to no risk of transmitting infectious disease because, for example, they do not include biological materials such as materials from a cadaver, and being relatively inexpensive. (See, e.g., page 9 of the specification.)

The Examiner rejected claims 1-11 under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,385,887 (Yim). As acknowledged by the Examiner, Yim discloses a composition having, among other things, an osteogenic protein and materials, such as a polymer matrix component to provide in situ scaffolding for the osteogenic protein, and autogenous blood. But when these materials are combined with the claimed compositions, the resulting combined composition would not be covered by claims 1-11, with their "consisting essentially of" language.

Indeed, these materials would materially change the claimed compositions because the claimed compositions could not be used as a versatile base. For example, if a surgeon wants to add demineralized bone (a source of osteogenic protein) to the claimed compositions, the presence of Yim's osteogenic protein in the compositions can affect how much demineralized bone can or should be added to the compositions. The polymer matrix component adds another variable in the control of the compositions' biodegradation, and autogenous blood can affect the consistency, and therefore, the performance, of the compositions. In some applications, the addition of these materials can be disadvantageous because, e.g., they can undesirably affect the compositions' set up time, hardness,

and biodegradation. The addition of the materials described by Yim would limit, and therefore materially affect, the function of the claimed compositions.

Since Yim does not disclose or suggest a composition consisting essentially of calcium sulfate, a mixing solution, and a plasticizing substance, Applicants request that the rejection be reconsidered and withdrawn.

The Examiner rejected claims 1-15 under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 5,356,629 (Sander) combined with U.S. Patent No. 4,619,655 (Hanker). In particular, the Examiner relied on Sander for disclosing a composition having a matrix, such as a cellulose ether, and a liquid medium, and Hanker for disclosing a composition having calcium sulfate hemihydrate.

As acknowledged by the Examiner, Sander discloses use of calcium sulfate hemihydrate in a bone graft composition, but Sander teaches away from using calcium sulfate hemihydrate. Sander characterizes a composition having calcium sulfate hemihydrate as having undesirable workability and bioresorption:

> For example, plaster of paris [calcium sulfate hemihydrate] will tend to lose its workability and set hard within five to ten minutes after mixing with water, making it difficult to mold over an extended period of time to properly fit within a bone defect. Additionally, plaster of paris can take over one month to be resorbed after implantation into a bone defect, which limits the rate at which bone-forming cells can take the place left by resorbed plaster of paris. (See Sander at col. 1, lines 30-38.)

It is particularly telling that even though, at column 1, line 18, Sander directly cites Hanker (U.S. Patent No. 4,619,655) for disclosing use of calcium sulfate hemihydrate, Sander does not include calcium sulfate hemihydrate in his composition. Sander was evidently aware of Hanker and discloses the use calcium sulfate hemihydrate, yet Sander teaches away from using calcium sulfate hemihydrate. Clearly, there is no motivation to combine calcium sulfate hemihydrate with Sander's composition.

In fact, instead of using calcium sulfate hemihydrate, Sander uses a matrix material, such as a cellulose or collagen, to provide his composition with his desired workability, resorption, and hardness upon setting. Sander contrasts his composition with one having calcium sulfate hemihydrate:

> The composition of the present invention, when wetted, will not set into a rock hard material like plaster of paris which, when wetted, begins to set and lose workability within five to ten minutes. Therefore, the composition of the present invention retains workability or moldability characteristics for an extended period of time after being wetted, resulting in improved overall handling characteristics and ability to be shaped upon implantation into a bone defect site. Furthermore, the matrix in the composition of the present invention can be resorbed fairly rapidly upon implantation into a bone defect site, e.g., within about ten to fourteen days after implantation, permitting faster ingrowth of osteogenic cells as bone tissue is regenerated. (See Sander at col. 2, lines 14-27.)

Compared to Sander's description of a composition having calcium sulfate hemihydrate (block quoted above), it is clear that Sander is using the matrix material to give his composition different characteristics than those of a composition having calcium sulfate hemihydrate. That is, Sander is using the matrix material instead of using calcium sulfate hemihydrate. Thus, rather than providing motivation to add the matrix material to a calcium sulfate hemihydrate composition as suggested by the Examiner, Sander provides motivation to leave out calcium sulfate hemihydrate and replace it with the matrix material to provide his composition with different performance characteristics.

Moreover, even if Sander and Hanker could be properly combined, which Applicants do not concede, the combination would not produce the claimed composition. For example, a combination of Sander and Hanker would produce a composition having a plurality of biocompatible particles, such as xenograft bone and homologous bone, dispersed in the matrix material since Sander discloses his composition as having such particles for bone repair. As discussed above, these materials would materially change the claimed compositions because, e.g., the claimed compositions could not be used as a customizable base. When materials such as xenograft bone and homologous bone are combined with the claimed, the combined composition would not be covered by claims 1-15.

For at least these reasons, claims 1-15 are patentable over Sander and Hanker. Applicants request that the rejection be reconsidered and withdrawn.

The Examiner provisionally rejected claims 1-15 under the judicially created doctrine of obviousness-type double patenting over claims 2, 3, 8, and 12-38 of co-pending Application No. 09/327,761. The rejection is provisional because the claims have not been allowed, so Applicants

will address this rejection, e.g., by filing an appropriate terminal disclaimer, upon an indication that the claims are otherwise patentable.

New claims 16-27 recite a composition consisting of calcium sulfate, a mixing solution, and a plasticizing substance. Claims 16-27 are patentable over the cited references for at least the same reasons that claims 1-15 are patentable over the cited references.

Applicants believe the claims are in condition for allowance, which action is requested. Enclosed is a $126.00 check for excess claim fees.

Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: May 9, 2002

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